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मानक

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“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 7531 (1990): Surgical Instruments - Corrosion Resistance
of Stainless Steel Surgical Instruments - Methods of Tests
[MHD 1: Surgical Instruments]



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“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक

शल्यक उपकरण — स्टेनलैस स्टील से बने शल्यक
उपकरणों के संक्षारण प्रतिरोध की परीक्षण पद्धतियाँ

(पहला पुनरीक्षण)

Indian Standard

SURGICAL INSTRUMENTS — CORROSION
RESISTANCE OF STAINLESS STEEL SURGICAL
INSTRUMENTS — METHODS OF TESTS

(*First Revision*)

UDC 615·471 : 669·14·018·8 : 620·193·52

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BUREAU OF INDIAN STANDARDS
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FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 20 December 1990, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1975 and covered boiling and autoclaving tests for corrosion resistance on stainless steel surgical instruments. In this revision, the requirements for boiling test have been modified and a new test, namely copper sulphate test has been added in line with ISO 7151 : 1988 'Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods', issued by the International Organization for Standardization (ISO).

Clause 3 of this standard permits the purchaser to use his option for selection of the tests to suit his requirements.

In reporting the results of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'.

Indian Standard

SURGICAL INSTRUMENTS — CORROSION RESISTANCE OF STAINLESS STEEL SURGICAL INSTRUMENTS — METHODS OF TESTS

(*First Revision*)

1 SCOPE

This standard specifies the methods for testing of corrosion resistance of surgical instruments made from stainless steel.

2 REFERENCES

IS 1070 : 1977 'Water for general laboratory use (*second revision*)' forms a necessary adjunct to this standard.

3 TYPE OF TESTS

The following tests are specified for determining the corrosion resistance:

- a) Copper Sulphate Test
- b) Boiling Water Test
- c) Autoclaving Test

The purchaser shall specify whether all the tests are to be carried out, or if not, which of the tests are to be performed. If the purchaser does not so specify, it is left to the discretion of the manufacturer as to which test to apply.

4 COPPER SULPHATE TEST

4.1 Apparatus

Glass or ceramic beaker.

4.2 Reagents

4.2.1 Copper (II) Sulphate Pentahydrate

4.2.2 Sulphuric Acid (*rd 1'84*)

4.2.3 Distilled Water

Conforming to IS 1070 : 1977.

4.3 Preparation of Test Solution

Dissolve 4 g of copper sulphate (4.2.1) in 10 g of sulphuric acid (4.2.2). Cautiously, add the above to 90 ml of distilled water (*see* 4.2.3) taken in glass or ceramic beaker (4.1).

4.4 Preparation of Sample

Scrub the surgical instrument using soap and water, rinse thoroughly in distilled water, dip in 95 percent (*v/v*) ethanol and dry.

4.5 Procedure

Immerse the surgical instrument in the test solution (4.3) at room temperature for 6 min. Remove the instrument and wash it with distilled water or wipe it with wet cotton wool. Examine the instrument for evidence of deposition of copper. Except as specified under 4.5.1, there shall be no plating of copper on the instrument.

4.5.1 Slight deposit of copper on the periphery of the instrument, or at the soldered or brazed junctions or dulling of polished surfaces caused by copper sulphate solution shall be disregarded. Similarly, slight plating of copper in small parts of joints, ratchets and serrations shall be disregarded.

5 BOILING WATER TEST

5.1 Reagent

Distilled water conforming to IS 1070 : 1977.

5.2 Apparatus

Glass or ceramic beaker or suitable corrosion resistant stainless steel vessel.

5.3 Preparation of Sample

Scrub the instrument using soap and warm water, rinse thoroughly in distilled water (5.1) and dry.

5.4 Procedure

Immerse the instrument in boiling distilled water (*see* 5.1) in the beaker or vessel for at least 30 min. Subsequently allow the instrument to cool for at least 1 h in the water used for the test. Remove the instrument from the water and leave it exposed to the air for 2 h.

5.5 Rub the instrument vigorously with a dry cloth and examine it for the presence of blemishes or other signs of corrosion. Any blemish not removed by vigorous hand rubbing with a cloth shall be considered as evidence of corrosion.

6 AUTOCLAVING TEST

6.1 This test shall be performed subsequent to the boiling water test.

6.2 Autoclave

A suitable autoclave of the non-vacuum type, with a minimum performance of 134°C and 200 kN/m² (2.04 kgf/cm²).

6.3 Water for Autoclaving Test

It shall conform to IS 1070 : 1977.

6.4 Procedure

After cooling the instrument to room temperature following the boiling water test, place it

unwrapped in a tray of the autoclave. Subject the instrument to six separate cycles of autoclaving each for $3 \pm \frac{1}{2}$ minutes at a minimum temperature and pressure of 134°C and 200 kN/m² (2.04 kgf/cm²) respectively. After each cycle, open the autoclave, remove the instrument and tray and allow it to cool to room temperature.

6.5 Wipe the instrument with a dry cloth and inspect for any visible signs of corrosion. Any blemish not removed by vigorous hand rubbing with a cloth shall be considered as an evidence of corrosion.

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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